

CLAIMS

I claim:

1. A method for producing a pharmaceutical piston stopper (2) made substantially from an elastomer and comprising a receiving cavity (6) for connecting with a displacement transferring
5 element and a piston section (8) enclosed in a cap-shaped inert film (9'), the piston section in a working position facing contents of a syringe or carpule cylinder (1), an outer circumference of the piston section with its inert film (9') abutting against the syringe or carpule cylinder (1), the piston stopper (2) having an uncoated sealing section (10) adjacent to the piston section (8), the method comprising:
10 placing a layered arrangement comprising a non-vulcanized rubber sheet (7) and an inert film (9) into a forming tool and forming the layered arrangement into a piston stopper under the influence of pressure and heat during a forming operation, wherein the rubber sheet (7) is vulcanized and joined with the inert film (9) in a non-detachable manner;
forming the complete contour of the piston stopper (2) during the forming operation from
15 the layered arrangement up to a layered arrangement flange (16) protruding laterally beyond the piston stopper (2) and remaining in a region of a partition plane of the forming tool;
producing the receiving cavity (6) in the rubber sheet (7) beyond the flange (16) in the piston section (8) during the forming operation;
displacing at least a wall region of the sealing section (10) bordering the receiving cavity (6)
20 and protruding beyond the flange (16) into a receiving cavity (6) during a separating operation; and
separating the piston stopper (2) from the flange (16) by a blanking operation, so that in the sealing section (10) an annular continuous sealing zone (13) is formed that directly adjoins an edge of the inert film (9') that envelopes the piston section (8), the sealing zone in a working position abutting against the syringe or carpule cylinder (1).
25 2. The method according to claim 1, wherein during the forming operation at least one annular continuous sealing lip (11) is formed on an outer circumference of the sealing section (10), and wherein the sealing lip (11) is displaced toward the receiving cavity (6) during the separating operation.

3. The method according to claim 1, wherein in the separating operation the at least one piston section (8) is placed centered into an opening (28) of a cutting die (27) and the flange (16) bordering the piston stopper (2) is clamped between the cutting die (27) and a clamping plate (29), wherein a portion of the sealing section (10) which projects beyond the flange (16) engages a pass-through opening (30) provided in the clamping plate (29), and wherein afterwards the wall region of the sealing section (10) bordering the receiving cavity (6) of the piston stopper (2) is displaced by a cutting punch (32) into the receiving cavity (6) and the flange (16) is blanked off the piston stopper (2).
4. The method according to claim 3, wherein the cutting punch (32) is moved in a direction from the free end of the sealing section (10) toward the flange (16) to separate the piston stopper (2) from the flange (16).
5. The method according claim 1, wherein the rubber sheet (7) is continuously sealed on its outer edge against at least one die plate (14, 15) of the forming tool on which it rests, and wherein during and/or after the opening of the forming tool to release the vulcanized layered arrangement from the die plate (14, 15) a gas is injected between the die plate and the layered arrangement.
6. The method according to claim 5, wherein the step of sealing the vulcanized layered arrangement against the die plate (14, 15) during the forming operation comprises forming a seal on an outer edge of the layered arrangement (22), the seal tightly abutting against the die plate (14, 15) and being continuous around the layered arrangement.
7. A device for producing pharmaceutical piston stoppers (2) made substantially from an elastomer and comprising a receiving cavity (6) for connecting with a displacement transferring element and a piston section (8) enclosed in a cap-shaped inert film (9'), the piston section in a working position facing contents of a syringe or carpule cylinder (1), an outer circumference of the piston section with its inert film (9') abutting against the syringe or carpule cylinder (1), the piston stopper (2) having an uncoated sealing section (10) adjacent to the piston section (8), the device being adapted to carry out the method according to claim 1 and comprising:
- a forming tool to form the piston stopper (2) from a layered arrangement comprising a non-vulcanized rubber sheet (7) and an inert film (9), wherein the forming tool has at least one first die plate (14) and a second die plate (15) interacting with the first die plate, which can be displaced relative to one another into closed and open positions;

a blanking device (26) to separate the piston stoppers (2) from a flange (16) laterally projecting beyond the piston stoppers (2) and remaining in a region of a partition plane of the forming tool, wherein the forming tool is constructed for forming of a complete contour of at least one piston stopper (2) up to the flange (16);

5 the first die plate (14) having at least one first cavity (17) fitting a form of the piston section (8) of the piston stopper (2) to be produced enveloped in a cap-shaped inert film (9) and the second die plate (15) having at least one second cavity (18) fitting a form of the uncoated sealing section (10) of the piston stopper (2);

10 the second cavity (18) having a form core (20) to form a receiving cavity (6) of the piston stopper (2) that can be connected with the displacement transferring element, the form core engaging with its free end the opposite situated first cavity (17) in a closed position of the forming tool;

 the blanking device (26) having a cutting die (27) with at least one orifice (28) for a central placement of the piston section (8); and

15 the cutting die (27) having a sleeve-shaped cutting punch (32) having a cutting edge on its outer circumference to separate the flange (16) from the piston stopper (2), the cutting punch being axially movable toward and away from the orifice (28) and having an inside cavity (34) constructed to accommodate an inwardly deformed sealing section (10) of the piston stopper (2).

8. The device according to claim 7, wherein the blanking device (26) has a clamping plate (29) with at least one pass-through orifice (30) aligned with one of the at least one orifice (28) of the cutting die (27) to accommodate the sealing section (10), wherein the clamping plate is axially displaceable relative to the cutting die (27) toward the orifice (28) to clamp the flange (16) between the clamping plate (29) and the cutting die (27), and wherein the cutting punch (32) is axially displaceably guided in the pass-through orifice (30) of the clamping plate (29).

25 9. The device according to claim 7, wherein a circumferential wall of the at least one second cavity (18) of the second die plate (15) has at least one annular continuous recess (21) to form an annular continuous sealing lip (11) on an outer circumference of the sealing section (10).

10. The device according to claim 7, wherein the cutting punch (32) has on its inside an entry slope (33) at its free end facing the cutting die (27).

11. The device according to claim 7, further comprising a continuous seal (22) around the layered arrangement to seal an outer edge of the vulcanized layered arrangement against at least one die plate (14, 15), and a gas supply channel (24) opening into a region of the die plate bordered by the seal, the gas supply channel being connected to a source of pressurized gas for detaching the layered arrangement from the die plate (14, 15).

12. The device according to claim 11, wherein for formation of the seal (22) at least one die plate (14, 15) has inside its form cavity an annular groove (23) bordering the respective cavities (17, 18) of the die plate (14, 15) with a spacing.

13. The device according to claim 11, further comprising a valve (25) provided in an entry region of the gas supply channel.

14. The device according to claim 13, wherein the valve (25) is a disc valve.

15. A pharmaceutical piston stopper (2), comprising a base body (7') made substantially from an elastomer and comprising a receiving cavity (6) for connecting with a displacement transferring element and a piston section (8) enclosed in a cap-shaped inert film (9'), the piston section in a working position facing contents of a syringe or carpule cylinder (1), an outer circumference of the piston section with its inert film (9') abutting against the syringe or carpule cylinder (1), the piston stopper (2) having an uncoated sealing section (10) adjacent to the piston section (8), the uncoated sealing section abutting in the working position against the syringe or carpule cylinder (1) and having at least one continuous sealing lip (11) on its outer circumference, wherein the base body (7') is made in one piece, with the receiving cavity (6) extending up into the piston section (8), and wherein the sealing section (10) has on its outer circumference an annular continuous sealing zone (13) directly adjacent to an edge of the inert film (9') enveloping the piston section (8), the sealing section in the working position abutting flat against the syringe or carpule cylinder (1).

16. The pharmaceutical piston stopper (2) according to claim 15, wherein the sealing zone (13) is provided as a straight extension to an outer circumferential section of the inert film (9') that in the working position abuts against the syringe or carpule cylinder (1) or slightly projects beyond the outer circumferential section.

17. The pharmaceutical piston stopper (2) according to claim 15, wherein a section (6a) of an inside wall of the piston stopper (2) bordering the receiving cavity (6) has an internal thread to connect with a thread of the displacement transferring element, and the internal thread terminates at a spacing from a bottom (6b) of the receiving cavity (6).

18. The pharmaceutical piston stopper (2) according to claim 17, wherein the section (6a) with the internal thread terminates at the piston section (8) or at a spacing from it, and wherein a cylindrical or tapered receiving cavity (6c) joins the section (6a) with the internal thread with the receiving cavity extending into the piston section (8).
- 5 19. The pharmaceutical piston stopper (2) according to claim 15, wherein a cross-section of the receiving cavity (6) commencing from a bottom (6b) tapers out toward an opening of the receiving cavity (6).
20. The pharmaceutical piston stopper (2) according to claim 15, wherein the inert film (9') comprises a fluorinated polymer film.